



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Registration: Mallinckrodt, LLC

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Mallinckrodt, LLC applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mallinckrodt, LLC registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated September 16, 2015, and published in the *Federal Register* on September 23, 2015, 80 FR 57388, Mallinckrodt, LLC, 3600 North Second Street, Saint Louis, Missouri 63147 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, LLC to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Gamma Hydroxybutyric Acid (2010)	I
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) (9821)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II

<u>Controlled Substance</u>	<u>Schedule</u>
Sufentanil (9740)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacturer bulk active pharmaceutical ingredients (API) for distribution to its customers.

Dated: February 10, 2016

Louis J. Milione,
Deputy Assistant Administrator.